

EXHIBIT 37

**IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OHIO
EASTERN DIVISION**

IN RE NATIONAL PRESCRIPTION OPIATE
LITIGATION

This document relates to:

Track One Cases

MDL No. 2804

Case No. 17-md-2804

Hon. Dan Aaron Polster

DECLARATION OF JOSEPH TOMKIEWICZ

I, Joseph Tomkiewicz, declare, upon personal knowledge and under penalty of perjury, that the following is true and correct:

1. I am the DEA Compliance Manager at Teva Pharmaceuticals USA, Inc. (“Teva USA”), and have served in this role since I joined Teva USA in January of 2014. I have personal knowledge of the matters stated herein.

2. Prior to joining Teva USA, I had extensive experience in the pharmaceutical industry, particularly in the field of DEA compliance. I worked as a pharmacy technician and information technology consultant for a long-term care pharmacy before transferring to the corporate office of PharMerica (previously known as Pharmacy Corporation of America) in 1994. From 1999 to 2002, I worked as a regulatory affairs specialist for Bergen Brunswig, the corporation that acquired PharMerica. As a regulatory affairs specialist, I was responsible for performing on-site regulatory audits for Bergen Brunswig owned pharmacies, among other things. In 2008, I joined AmerisourceBergen as a corporate investigator. In that role, I managed AmerisourceBergen’s corporate investigations, anti-diversion, and suspicious order monitoring

programs until the fall of 2013. I am familiar with the rules and requirements under the Controlled Substances Act (“CSA”) and DEA regulations regarding suspicious order monitoring.

3. I have presented at various conferences on the topic of suspicious order monitoring systems over the past few years, including at the PDMA 17th Annual Controlled Substance & State Regulatory Conference (April 2014) and the 27th and 28th Annual Sharing Conferences presented by the Sharing Alliance (October 2017 and September 2018).

4. Teva USA became affiliated with Cephalon, Inc. (“Cephalon”) in October of 2011. Cephalon utilizes Teva USA’s SOM program and has done so since approximately October 2011.

5. Teva USA is and has always been committed to preventing diversion of controlled substances, including opioids, that it manufactures and sells. As far as I am aware, Teva USA has always had a DEA Compliance department and a SOM system in place to identify, monitor, investigate, and, if necessary, report potentially suspicious orders to the DEA. Likewise, Teva USA has also had controls in place to prevent the theft or diversion of opioids, including controls to ensure the proper manufacturing, storage, treatment, and handling of controlled substances. Teva USA has maintained and currently maintains a robust system to identify, monitor, investigate, and, if necessary, report potentially suspicious orders to the DEA.

6. Teva USA has adhered and continues to adhere to DEA guidelines defining a “suspicious order” as including orders of unusual size, orders that deviate from a normal ordering pattern, and orders of unusual frequency.

7. Teva USA had monitored and continues to monitor industry trends, DEA and other regulatory guidance, media reports, and public records searches to ensure that it understands the business operations of its customers.

8. I oversaw the development of Teva USA's current SOM program, the Defensible Order Pending System ("DefOPS"), in 2014 and its implementation in March of 2015. It is a statistically-based computerized order review system that runs a proprietary algorithm against every order for any controlled substance, and certain non-controlled substances, to identify specific orders that should be reviewed, analyzed and investigated by the DEA Compliance team. The system employs "review parameters" based on Teva USA's twelve month rolling order history by DEA Drug Code or Basic Class of Substance, active ingredient by weight in grams, and customer peer group. That system remains in place today, though Teva USA continues to update the system.

9. For every controlled substance order that Teva USA receives, the DefOPS system analyzes the order by comparing it and the total weight of API ordered by the customer for the past twelve months (based on most recent quarterly data) to the customer's previous orders, as well as comparable customers' orders for the same period. If the order falls outside the expected parameters, DefOPS identifies the particular order as requiring manual review by trained investigators, thereby initiating a review of the specific order by the DEA Compliance team. All orders held for manual review are pended in Teva USA's order system until DEA compliance manually reviews the orders and determines whether it should be filled, investigated further, or canceled and reported to the DEA. No customer is exempt from this process. The review determines whether there are legitimate explanations for the factors that caused the order to be held for manual review.

10. Teva USA primarily sells and has sold opioid medicines to wholesale distributors, which are DEA registrants. Teva USA knows its customers and their order histories and patterns. When I began at Teva USA, it had not had a new customer approved or brought on for

several years prior. Before shipping opioid medicines to a customer, Teva USA has always analyzed each order by comparing it to that customer's prior order patterns for the past twelve months and to order patterns of other comparable customers for the same time period. Teva USA also confirms prior to shipment that each customer is registered to possess controlled substances. Teva USA understands that its customers have sophisticated SOM systems in place to identify and report suspicious orders consistent with their obligations under the CSA and DEA regulations. Teva USA expects that its customers will comply with their obligations and will not purchase more product than necessary to fill appropriate orders from their customers to dispense medically appropriate prescriptions.

11. Based upon my knowledge of its SOM systems, Teva USA has always had a system in place to investigate orders that are flagged as potentially suspicious. Under Teva USA's DefOPS system, if an order is flagged as requiring further investigation (and therefore not shipped), the DEA Compliance group manually investigates the order. That manual review process may include reviewing the customer's purchase history for the previous 12 months (focusing specifically on size, pattern, and frequency) and reviewing the customer's history regarding compliance. The DEA Compliance team makes a determination based on, among things, the customer's response, the geographic location of the customer, the type and quantities of products forecasted for purchase, and an investigation into whether the new customer or any of its principals is on Teva USA's "Do Not Ship List." Teva USA's DEA Compliance department also conducts public records searches and utilizes Google Earth and/or site visits, both announced and unannounced, before agreeing to fill orders for new customers.,

12. As part of this manual review process, Teva USA contacts the customer who placed the order via the Teva USA customer service representative, under the guidance of DEA

compliance, who has a relationship with that customer. This not a flaw in the system. The customer service representative who is familiar with the facility, had prior contact with the customer, and knows the customer is in the best position to gather relevant information about the order (and customer) to relay to DEA Compliance to make its determination about whether the order is suspicious. If necessary, multiple individuals in DEA Compliance are involved with a deeper investigation into the order. Teva USA customer service representatives did not and do not make any decisions regarding what happens to the flagged order. Teva USA's DEA Compliance group makes all final decisions with respect to whether to release or report flagged orders. Those decisions are then reviewed regularly.

13. If the DEA Compliance group determines that there is no reasonable explanation for a flagged order after investigation, it is deemed a "suspicious order." Any such "suspicious order" is reported to the local DEA field office in writing within 24 hours of completion of the investigation. The report includes the following information: (1) date of order; (2) name, address and registration number of the customer; (3) name, strength and quantity of product ordered; and (4) reason the order was deemed suspicious.

14. Based upon my understanding of the history of Teva USA's SOM Program, Teva USA has always had procedures in place to identify, monitor, investigate, and, if necessary, report potentially suspicious orders to the DEA. While those procedures were formally reduced to writing in one place in 2014, they have long been in existence. It is my understanding that prior to 2014, Teva USA had SOM procedures in place even though they were not reduced to writing.

15. In 2015, shortly after the DefOPS program was implemented, there was a global internal audit of Teva USA's DEA compliance program. The auditor noted that there was a

potential risk associated with giving one person authority to review orders held for manual review. I am not aware of any such mistakes made with respect to the release of flagged orders. Moreover, in 2015, review of flagged orders by one person was manageable at that time given the relatively low volume of orders. At that time, Teva USA had less than 200 customers who purchased controlled substances from Teva USA. In August 2016, Teva USA became affiliated with various generic manufacturers that were previously owned by Allergan plc (collectively, “Actavis Generic Entities”).¹ Shortly thereafter, the Actavis Generic Entities’ generic controlled substances and certain non-controlled substances acquired through the transaction (and orders for those products) were all integrated into Teva USA’s SOM system. Since at least August 2016, there have been multiple layers of review of orders held for manual review within Teva USA and multiple persons involved in the review of such orders, in part because of the increased volume of orders of controlled substances.

16. Teva USA communicates with the DEA regarding suspicious order monitoring. The DEA has never communicated to Teva USA that its SOM system was inadequate to comply with the CSA or DEA regulations or guidance. Nor has the DEA taken any enforcement action with respect to suspicious order monitoring against Teva USA.

17. Teva USA continues to develop its own technology and processes to stay ahead of the curve in combatting diversion as much as possible given the information available to it, requirements under the law, and guidance from the DEA.

18. Teva USA has identified and reported numerous orders to the DEA that are suspicious, after investigation by the company into the circumstances of the order. For example,

¹ They include Watson Laboratories, Inc., Actavis LLC, Actavis Pharma, Inc., Warner Chilcott Company, LLC, Actavis South Atlantic LLC, Actavis Elizabeth LLC, Actavis Mid Atlantic LLC, Actavis Totowa LLC, Actavis Kadian LLC, Actavis Laboratories UT, Inc. f/k/a Watson Laboratories, Inc.-Salt Lake City, and Actavis Laboratories FL, Inc., f/k/a Watson Laboratories, Inc.-Florida

DEA Compliance declined and reported a suspicious order for hydrocodone when an investigation into the ordering company showed that the owner had recently pled guilty to several felonies related to the sale of misbranded pharmaceuticals. Teva USA held all other orders by the company and notified the DEA that it ceased all sales of controlled substances to the company. The DEA has never communicated that either the number or content of Teva USA's reports are inadequate or unacceptable in any way.

19. Based upon my experience and knowledge, Teva USA and Cephalon have always complied with their obligations under the Controlled Substance Act with respect to suspicious order monitoring and preventing diversion.

20. I am not aware of any suspicious order placed with Teva USA or Cephalon that should have been, but was not, brought to the attention of the DEA, much less any such order for an opioid shipment into Ohio or elsewhere.

Pursuant to 28 U.S.C. § 1746(1), I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Dated: July 30, 2019

By:



Joseph Tomkiewicz